

**Remarks:**

Reconsideration of the application in view of the above amendments and following remarks is requested. Claims 55-60 are now in the case. Claims 15-22 and 74-80 have been canceled. Applicants reserve the right to prosecute claims to cancelled subject matter in one or more continuing applications.

**I. Continued Examination Under 37 CFR 1.114 (*regarding part 1 of the Office Action dated February 1, 2008, hereinafter, the present Office Action*)**

The Examiner has accepted Applicants' request for continued examination under 37 CFR 1.114. Also, the Examiner has acknowledged that Applicants' submission filed on December 7, 2007 has been entered including the declaration under 37 CFR §1.132 of Dr. WenFeng Xu.

**II. Status of the Claims (*regarding part 2 of the present Office Action*)**

The Examiner has acknowledged Applicants' amendment to the claims filed on December 7, 2007.

The Examiner has advised that claims 74-80 do not fulfill the requirements of the election/restriction response and has thus withdrawn said claims from examination. Applicants have cancelled claims 74-80.

**III. Claims Rejections – 35 U.S.C. §103 (*regarding parts 3-7 of the present Office Action*)**

*A. Regarding Part 4 of the Present Office Action*

The Examiner has advised Applicants of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claims that was not commonly owned at the time a later invention was made, in order for the Examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §102(e), (f), or (g) prior art under 35 U.S.C. §103(a).

*B. Regarding Parts 3, 5, and 6 of the Present Office Action*

The Examiner has rejected claims 15-18, 20-21, 55-57, and 59 under 35 U.S.C. §103(a) as being unpatentable over Busfield (US 2002/0164689A1) in view of Hopp et al. (Hopp, TP and Woods, KR, Proc. Natl. Acad. Sci. USA, 78:3824-28, 1981) and in further view of Lok et al. (U.S. Pat. No. 5,965,704).

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To simplify matters under consideration, Applicants have canceled claims 15-22. Thus, the rejection as it relates to claims 15-18 and 20-21 is rendered moot as applied thereto.

With regard to claims 55-57 and 59, **Applicants respectfully traverse**. Obviousness requires that “the prior art reference (or references when combined) must teach or suggest all the claim limitations.” See MPEP 706.02(k); MPEP 2143; and MPEP 2143.03 *citing In re Royka*, 490 F.2d 981 (CCPA 1974) (emphasis added). The elements recited in the present claims are not all taught or suggested in the prior art references that the Examiner has cited.

Specifically, the present claims recite an antibody or antibody fragment that binds to an antigenic epitope of human IL-22RA (SEQ ID NO:3), amino acid number 1 (Pro), to amino acid number 6 (Asp) of SEQ ID NO:3. None of the references cited by the Examiner teach the specific limitation that the antibody should bind to amino acid number 1 (Pro), to amino acid number 6 (Asp) of SEQ ID NO:3.

Moreover, the cited references do not properly suggest the specific limitation that the antibody should bind to amino acid number 1 (Pro), to amino acid number 6 (Asp) of SEQ ID NO:3. The Examiner has suggested that since Hopp et al. teaches that the best antigenicity is obtained using hexapeptides rich in P, E, and D, the PEDPSD hexapeptide would be an obvious epitope choice in light of the sequence disclosure in Busfield. However,

It is improper to combine references where the references teach away from their combination.

MPEP 2145 citing *In re Grasselli*, 713 F.2d 731 743 (Fed. Cir. 1983).

Applicants respectfully reiterate that **Busfield can not be combined with Hopp et al. because Busfield teaches away from Hopp et al.** (Applicants first made this argument in the Amendment dated February 15, 2007.) Busfield is cited by the Examiner because it teaches SEQ ID NO:2. However, Busfield goes on to teach that antigenic peptide fragments of SEQ ID NO:2 should

... comprise at least 8 (preferably 10, 15, 20, or 30) amino acid residues of the amino acid sequence of SEQ ID NO:2...

See Busfield, paragraph [0169] (emphasis added). Thus, Busfield teaches away from Hopp et al., and one having ordinary skill in the art **would not** understand that the best antigenic fragments of the sequences disclosed in Busfield are hexapeptides (as disclosed

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in Hopp et al.); rather, one having ordinary skill in the art would understand that the best antigenic fragments should be longer, “at least 8 (preferably 10, 15, 20, or 30) amino acid residues” **because that is what Busfield teaches**. See Busfield, paragraph [0169].

Busfield can not be read in view of Hopp et al. at the expense of what Busfield explicitly teaches. The Examiner has stated in the Office Action dated May 7, 2007, that

... the argument that Busfield teaches away from the proposition that the best antigenicity is obtained using hexapeptides is rejected since Hopp et al. teach the requirements for best antigenicity... Busfield does not provide a detailed analysis (just that the peptide to be located in a hydrophilic region and the fragment)...

However, Applicants respectfully submit that it is improper for the Examiner to maintain the rejection based on said reasoning because said reasoning ignores the explicit disclosure in Busfield. Busfield does not merely teach that the peptide should be located in a hydrophilic region, as the examiner has suggested. Rather, Busfield also teaches that the antigenic peptide fragments should comprise “at least 8 (preferably 10, 15, 20, or 30) amino acid residues”. See Busfield, paragraph [0169]. The Examiner is not at liberty to ignore this explicit teaching of Busfield. A 35 U.S.C. §103(a) rejection can not properly be based on hand selected elements of disclosure in the prior art that are contrary to what the references actually teach as a whole. Applicants are not attacking the references individually, as the examiner has previously suggested, rather Applicants are attacking the combination of the references because said combination is improper as it ignores the full teachings of Busfield.

Consequently, none of the prior art references teach or suggest all of the claim limitations, and the present claims are not obvious in view of the cited references. Thus, Applicants respectfully request that the Examiner properly withdraw the current 35 U.S.C. §103(a) rejection of claims 55-57 and 59.

*C. Regarding parts 3, 5, and 7, of the present Office Action*

The Examiner has rejected claims 19, 22, 58, and 60 under 35 U.S.C. §103(a) as being unpatentable over Busfield, in view of Hopp et al., and in further view of Lok et al., and Gonzales et al. The Examiner has alleged that it would have been obvious to one skilled in the art to modify the antibodies by PEGylation based on either Busfield or Lok et al. in view of Hopp et al. in order to increase the serum half-life, as taught by Gonzales et al.

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To simplify matters under consideration, Applicants have canceled claims 15-22. Thus, the rejection as it relates to claims 19 or 22 is rendered moot as applied thereto.

With regard to claims 58 and 60, **Applicants respectfully traverse.** The MPEP instructs that

If an independent claim is nonobvious under 35 U.S.C. 103, then any claim dependent therefrom is nonobvious.

See MPEP 2143.03 *citing In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988). In the arguments presented above, Applicants have shown that independent claim 55 is non-obvious over either Busfield or Lok et al. in view of Hopp et al. Accordingly, the claims dependent therefrom (including claims 58 and 60) are likewise nonobvious over either Busfield or Lok et al. in view of Hopp et al.

Consequently, the present claims are not obvious in view of the cited references and Applicants respectfully request that the Examiner withdraw the current 35 U.S.C. §103(a) rejection of claims 58 and 60.

#### **IV. Double Patenting (regarding Parts 8-10 of the present Office Action)**

The Examiner has provisionally rejected claims 15-22 and 55-60 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8-22 and 55-60 of co-pending Application Nos. 11/256,499 and 11/350,375.

Upon an indication of otherwise allowable subject matter and in the event that these rejections are maintained for the pending claims, Applicants will provide an appropriate response.

#### **V. Conclusion**

On the basis of the above amendments and remarks, Applicant believes that each rejection has been addressed and overcome. Reconsideration of the application and its allowance are requested. If for any reason the Examiner feels that a telephone conference would expedite prosecution of the application, the Examiner is invited to telephone the undersigned at (206) 434-3410.

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The remainder of the fee for the 3 month extension of time will be paid online via EFS. It is believed that no other fee is due; however, in the event that another fee is due, please charge any fee or credit any overpayment to Deposit Account No. 26-0290.

Respectfully Submitted,



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Registration No. 60,106

Enclosure:

Petition and Fee for Extension of Time

Customer No. 10117

ZymoGenetics, Inc.